

August 17, 2006

Mr. Janzing, M.,
European Patent Office,
P.B. 5818, Patentlaan 2,
NL-2280 HV Rijswijk – Pays Bas.
The Netherlands

BY FAX & REGD. MAIL
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TOTAL PAGES : ()

Dear Sir,

Subject: Your Notification of Transmittal of the International Preliminary Report on Patentability dated 17.07.2006 in the matter of **PCT/IN2004/000142** entitled "AN IMPROVED PROCESS FOR PRODUCING CHLORINATED SUCROSE". applicant Pharmed Medicare Pvt. Ltd., Pharmed House, 141, Walchand Hirachand Marg, Mumbai 400 001 Maharashtra, India.

In the matter of above subject, we are writing you on behalf of the applicant Pharmed Medicare Pvt. Ltd. as their agents.

We thank you very much for sending us the International Preliminary Examination Report on Patentability mentioned above.

However, we did not receive even a single written opinion prior to the final report on International Preliminary Examination Report on Patentability although about 7 months were available after we submitted the Demand for International Preliminary Examination Report. This has resulted in loss of opportunity to the applicant to argue regarding some reasons provided by the Hon. Authorized officer and to make an amendment in claim by taking into consideration views expressed by the Hon. Authorized Officer.

We request to invite your kind attention to following provisions of PCT and regulations, the benefit of which was not received by the applicant:

1. Article 34 (2) (c) ("The applicant shall receive at least one written opinion from the International Preliminary Examining Authority---") and
2. Rule 66.2 of the PCT provided that " (a) If the International Preliminary Examining Authority, (i) -----, (ii) considers that the international preliminary examination report should be negative in respect of any of the claims because the invention claimed therein does not appear to be novel, does not appear to involve an inventive step (does not appear to be non-obvious), or does not appear to be industrially applicable, ----- the

said Authority shall notify the applicant accordingly in writing. ----- (b) The notification shall fully state the reasons for the opinion of the International Preliminary Examining Authority. (c) The notification shall invite the applicant to submit a written reply together, where appropriate, with amendments. (d) The notification shall fix a time limit for the reply. The time limit shall be reasonable under the circumstances. It shall normally be two months after the date of notification. In no case shall it be shorter than one month after the said date. It shall be at least two months after the said date where the international search report is transmitted at the same time as the notification. It shall, subject to paragraph (e), not be more than three months after the said date. (e) The time limit for replying to the notification may be extended if the applicant so requests before its expiration. 66.3 *Formal Response to the International Preliminary Examining Authority* (a) The applicant may respond to the invitation referred to in Rule 66.2(c) of the International Preliminary Examining Authority by making amendments or—if he disagrees with the opinion of that Authority—by submitting arguments, as the case may be, or do both.

In fact, in view of above provisions, since the applicant did not receive any written opinion during all this period, it was inferred that the Authority is in agreement with the amendments made and on Novelty, inventive step and Industrial applicability of the amended claims too.

However, the final report contains several reservations on above issues, and looking at the contents of the final International Preliminary Report on Patentability, the applicant feels that the reservations on allowing certain amendments and novelty and inventive step in certain claims could have been overcome effectively and to the satisfaction of the Hon. Authorized Officer by a combination of explanations, arguments and amendments which the applicant could have offered had the applicant been communicated these reservations through a reasoned written opinion quite early, for which sufficient time was available.

Hence, the applicant endeavors to send his response with arguments and suggested amendments with an earnest and humble request to:

1. take the applicant's response accompanying this letter on your record and consideration,
2. if possible, revise your reservations on novelty and inventive step about the amended claim nos. 24 and 25, and on allowing insertion of the extra material and claim nos. 25 to 31 as amendments as explained in more details in the accompanying statement. If there are any reservations yet, the applicant shall welcome a second written opinion and the applicant is

ready even at this stage to interact for a conclusive result. Anyway, the applicant is constrained to move ahead for National Phase right now, and is prepared to await for final outcome of conclusive result if interaction is still possible to continue.

If the available time or any other reason does not permit consideration again, this response may please at least be kept on your record, and if possible, be sent to the countries elected so that they will know that we were under a disadvantage of not having received written opinions and that there are arguments and amendments which were eligible to be taken into consideration in the International Preliminary Examination phase but did not get due consideration and they may then take them into kind consideration in the National Phase without having an impression that the International Preliminary Report on Patentability had received all the due chance of interaction.

Please take note of attached documents on:

1. Statement of Response on Preliminary Examination on Report on Patentability.
2. Claim 24 as amended in response to the IPRP with amendment highlighted.
3. Clean copy of amended claim.

Regards.

For KRISHNA & SAURASTRI

(VASANT ANANTRAO SAVANGIKAR)

Enclosures:

1. Statement of Response on Preliminary Examination on Report on Patentability.
2. Claim 24 as amended in response to the IPRP with amendment highlighted.
3. Clean copy of amended claim.

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Statement of Response to
International Preliminary Report on Patentability
related to
PCT/IN2004/000142

With reference to International Preliminary Report on Patentability related to PCT/IN2004/000142, the applicant has humble explanations and an amendment to claim which the applicant is sure, would satisfy the Hon. Authorized Officer in waiving his objections to amended claim nos. 24 and 25 and in allowing amendment of description of the two extra figures on page 7, the extra materials of pages 23-26, new claims 26-31 and new figures 7 and 8. The applicant would have been very happy to give these explanations as soon as had the applicant received first written report of the Hon. Authorized Officer. However, whereas the applicant was entitled to receive three written at least, not a single one was received in fact. Hence, the applicant very politely requests the Authorized Officer kindly to consider this as a response to his written report no. 1 and take it in consideration and, if possible, revise the IPRP. Should this be not possible for any reason, this statement of the applicant may kindly be kept on record and sent to the elected countries.

With reference to the (Authorized Officer's) your Re Item I

Basis of the Report

With respect to your statement in para 1 that: "Amended claims 24 and 25 are considered allowable ---- or non-crystalline":

The applicant humbly states that: we welcome you having allowed the mentioned amendments.

With respect to your para 2 that "All other amendments however, being page 7 the description of the two extra figures, the extra material of pages 23-26, new claims 26-31 and new figures 7 and 8 are considered not-allowable (Rule

amendments. There can be no basis for new figures since those figures cannot be exactly the same as text, therefore, the content of those figures cannot have been present in the original application. The new added pages as well as the new claims 26-31 are also considered to extent the scope of the original application because the addition of particle sizes was not present at all (only one remark, page 23 line 14) where it is stated that the powders have smaller particle size. However, no numbers are specified, therefore, any added number is considered unallowable added matter.”:

The applicant requests to invite your attention very humbly to the following: The remark on page 23 line 14 opens the scope of all the amendments mentioned in above para. This remark as quoted from “as filed” specification is: “Solid powders obtained by ATFD and other methods of drying when compared to powders obtained from crystallization procedures were, however, amorphous in nature having smaller particle size.” As per Article 34 (2)(b), “(b) The applicant shall have a right to amend the claims, the description, and the drawings, in the prescribed manner and within the prescribed time limit, before the international preliminary examination report is established. The amendment shall not go beyond the disclosure in the international application as filed.” Just as amendment in claims means even insertion of new claims, provided they are within the scope of the specification, new figures can also be added in case not outside the scope of the disclosure, hence insertion of new figures nos. 7 and 8, in the sense of additional figures is compliant to provisions of PCT. Subject matter of the figure nos. 7 and 8 pertain to XRD spectra of crystalline and amorphous solid particle forms of trichlorogalactose (sucralose), whereas subject matter of the new added pages (part of page no. 23, and whole of page No. 24, 25 and page no. 26), and the new claims 26-31 either describe or are based on

fundamental physical properties of solid particles prepared by the process of claims 1 to 23. Being physical properties, they are integral part of the "particles" disclosed here, are not severable / separable from them and disclosure of these properties is "inherently" included even by mere disclosure of a mention of solid particles by the methods claimed, hence fully within the scope of disclosure of the "as filed" document. We are sure that this shall be to the satisfaction of the Hon. Authorized officer and he shall allow inclusion of all this newly added pages and claims in the specification because it is well settled principle that what is within scope of the "as filed" document, can be amended / added at the time of IPER, whether it be a description, a claim or a drawing.

With respect to your Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

With respect to your statement on Novelty in following two paragraphs that:

"The present application does not meet the criteria Article 33(2) PCT."
And

"The documents D1 and D2 disclose the synthesis and isolation of sucralose, thus claims 24 and 25 lack novelty since a product by process must be new and inventive. A product is not rendered novel merely by the fact that it is produced by a new process. Moreover, both D1 and D2 disclose crystalline sucralose (D1 page 293, sucralose was obtained as a syrup; D2 column 10 line 14 as a syrup) therefore, claims 24 and 25 are considered not novel.",

The applicant humbly invites kind attention of the Hon. Authorized Officer to the fact that the reference and entire description of amorphous product on page 23 of the "as filed" specification referred to "-----Solid powders obtained by ATFD and other methods of drying when compared to powders obtained from crystallization

particle "Form" known for chlorinated sucrose, particularly trichlorogalactosucrose (sucralose), is crystalline with long needles, the "as filed" as well as amended claim nos. 24 and 25 disclose a new "Form" of solid chlorinated sucrose solid particles, which, in varying proportions, is amorphous in part and microcrystalline in part with aggregate crystal size which is smaller than the conventional crystalline forms. To avoid "a syrup" also being included in this "amorphous" form claim, this applicant is prepared to make appropriate amendment in claim nos. 24 to make it clear that the claim pertains to "solid particles". This purpose shall be achieved by amendment in claim 24 as follows: **"A solid powder form of a chlorinated sucrose, its intermediates, its derivatives of process of claim 1 to claim 23, at least part of which is amorphous or non-crystalline."** This amendment gets automatically included in claims 25 and 26 through reference of claim 24 in them.

With respect to your comments on Inventive step:

The applicant is in agreement with the entire comments done by the Hon. Authorized Officer under the title "Inventive step".

With the explanations given with respect to "basis of Report" with respect to the new claims, new figures and new description being within the scope of the "as filed" application due to "inherent" reasons, we request the Authorized Officer to acknowledge Inventive step also to claim nos. 24 to 31 and Industrial applicability to claim nos. 26 to 31..

22. The process of claim 11 wherein the said impure solution is the solution of the solid powder mixture of several chemicals, including chlorinated sucrose, made in water and subjected to purification by application of separation methods including column chromatography, extraction in water immiscible solvent having selective affinity with chlorinated sucrose or chlorinated sucrose intermediates or chlorinated sucrose derivatives

23. The process of claim 11 when the said impure solution is the crude extract of chlorinated sucrose (or its intermediates or derivatives) from a solid powder mixture of several chemicals, including chlorinated sucrose; extraction being done by water and the water extract being subjected to a any suitable extraction process including to conventional extraction in any suitable solvent, including ethyl acetate, methanol, methyl ethyl ketone, acetone, which are capable of selective extraction of substantially pure form of chlorinated sucrose free from impurities.

24. **A solid powder form of a** chlorinated sucrose, its intermediates, its derivatives of process of claim 1 to claim 23, at a least part of which is amorphous or non crystalline.

25. Chlorinated sucrose, its intermediates, its derivatives of claim 24 produced by process of claim 1 to 23.

26. Chlorinated sucrose, its intermediates, its derivatives of claim 24 which comprises of :